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TITLE: A Randomized Effectiveness Trial of a Systems-Level Approach to Stepped Care for War-Related PTSD

PRINCIPAL INVESTIGATOR: Lisa H. Jaycox, Ph.D.

CONTRACTING ORGANIZATION: Rand Corporation  
Santa Monica, CA 90401

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14. ABSTRACT  During the last year, the study team continued follow-up data collection, boasting high retention rates. Three-month follow-up was completed in January 2014, with an overall completion rate of 93% across both arms. Six-month follow-up was completed in March 2014, with an overall completion rate of 90% across both arms. Twelve-month follow-up is projected to be completed by October 2014; the current overall completion rate is 86% across both arms. Investigators are prepared to conduct full analyses of the data as soon as the final two participants have completed the 12-month follow-up assessments. In the last year, all partnering institutions established data safeguarding plans and data transfer agreements to ensure datasets are properly transferred between institutions for data analysis. Investigators submitted a design manuscript to the journal <i>Contemporary Clinical Trials</i> and are preparing revisions to that manuscript. Investigators continued work on multiple manuscripts and presentations, including a main outcomes manuscript, and presentations on trial design at the 29 <sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2013 in Philadelphia, PA and at the Military Health System Research Symposium (MHSRS) in August 2014 in Ft. Lauderdale, FL.				
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## **INTRODUCTION:**

The purpose of the STEPS UP (STepped Enhancement of PTSD Services Using Primary Care) trial is to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care. We hypothesize that the STEPS UP intervention will lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; (3) costs and cost-effectiveness. We further hypothesize that qualitative data will show (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care.

STEPS UP is a six-site, two-parallel arm (N = 666) randomized controlled effectiveness trial with 3-month, 6-month, and 12-month follow-up comparing centralized telephonic stepped-care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP includes web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous RN nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred and available. The study uses sites currently running RESPECT-Mil, the existing military primary care-mental health services practice network, to access site health care leaders and potential study participants at the 6 study sites.

If effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so called "15 year science to service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

**KEYWORDS:**

Collaborative care, PTSD, military, depression, primary care, care management, stepped care, telehealth, OIF, OEF, preference-based treatment, cost effectiveness, web-based treatment, telephonic CBT, evidence-based treatment.

**OVERALL PROJECT SUMMARY:**

The STEPS UP study is currently in the follow-up data collection phase. The study team completed recruitment and enrollment of 666 participants (332 participants in the STEPS UP intervention arm; 334 participants in the Optimized Usual Care [OUC] arm) in August 2013. As of January 2014, 665 participants had exited the 3-month follow-up window (one participant was withdrawn due to incarceration); 618 participants completed the 3-month follow-up assessment (229 at JBLM, 106 at Ft. Bliss, 197 at Ft. Campbell, 17 at Ft. Carson, 46 at Ft. Stewart, and 23 at Ft. Bragg), for an overall 3-month follow-up completion rate of 93%. As of March 2014, all 665 participants had also exited the 6-month follow-up window; 600 participants completed the 6-month follow-up assessment (221 at JBLM, 104 at Ft. Bliss, 192 at Ft. Campbell, 15 at Ft. Carson, 45 at Ft. Stewart, and 23 at Ft. Bragg), for an overall 6-month follow-up completion rate of 90%. A total of 664 participants (one additional participant withdrawn due to incarceration) became eligible for the 12-month follow-up; 573 participants have completed the 12-month follow-up assessment (208 at JBLM, 102 at Ft. Bliss, 184 at Ft. Campbell, 15 at Ft. Carson, 42 at Ft. Stewart, and 22 at Ft. Bragg), for an overall 12-month follow-up completion rate of 86%. As of August 31, 2014, 2 participants, both at Ft. Campbell, are pending completion of the 12-month follow-up assessment (1 in the STEPS UP intervention arm and 1 in the OUC arm). We anticipate completing follow-up data collection early in the next quarter and then will conduct data analyses of the trial using all completed assessments.

Multiple amendments have been submitted to and approved by the WRNMMC IRB during the last year. In September 2013, the WRNMMC IRB approved an amendment to digitize consent forms and store them centrally at RTI for the required 6 year time period rather than storing the hard copies at their respective posts. In September 2013, the WRNMMC IRB full

committee reviewed an amendment to allow RTI to conduct batch tracing for lost-to-contact participants in order to get updated contact information to obtain follow-up data. The WRNMMC did not approve the amendment as written; instead, they suggested investigators update the consent form to reflect that batch tracing would be conducted and re-consent participants. However, investigators decided the costs associated with resubmitting the amendment and re-consenting participants were greater than the potential benefits of batch tracing and did not resubmit. In November 2013, the WRNMMC IRB and HRPO approved an amendment changing the study Initiating PI from COL Charles Engel to Dr. Michael Freed. Due to Dr. Engel's retirement from the military, he was advised to transition from Initiating PI to Collaborator on the study, and his transition to RAND was discussed with our project officer at the time, Jordan Irvin. He indicated that this transition was acceptable and that no administrative adjustments were necessary. In addition, the Henry M. Jackson Foundation (HJF) submitted an official request to our USAMRAA Contract Specialist (Mr. Lance Nowell) in August 2013 to change the PI, and responded to queries from Mr. Nowell to issue a modification with updates in February 2014 and March 2014. Issuance of the modification with updates is pending. In February 2014, the WRNMMC IRB approved an amendment which provided the DHCC Data Safeguarding Plan for data sharing. This plan describes how investigators at DHCC will obtain datasets from RTI and handle those datasets when conducting analyses. RAND, University of Washington, and BVARI have also received IRB approval from their institutions of their Data Safeguarding Plans. During the second quarter, RAND finalized a Data Transfer Agreement with RTI for the study datasets. During the third quarter, BVARI finalized their Data Transfer Agreement with RTI. During the fourth quarter, DHCC and University of Washington finalized their Data Transfer Agreement with RTI. All institutions now have access to the eligibility, baseline, 3-month, and 6-month datasets. We expect all institutions to have access to the 12-month dataset within the next quarter, once follow-up data collection is complete.

The WRNMMC IRB has also approved several site-specific amendments during the past year. In October 2013, the WRNMMC IRB approved an amendment adding a new STEPS UP care facilitator at Ft. Stewart. In November 2013, an amendment adding a new site Medical Monitor and site Associate Investigator at Ft. Campbell was approved. In April 2014, the WRNMMC IRB approved two amendments updating site personnel, including a new Medical

Monitor at Ft. Carson and updating the Site Coordinator and Nurse Care Facilitator at JBLM. Amendments adding new Site PIs at Ft. Bliss, Ft. Bragg, and Ft. Campbell were approved by WRNMMC IRB in July 2014.

During the last year, the lead WRNMMC IRB, all local site IRBs, and HRPO approved the study in continuing review; the WRNMMC protocol and each site package have a new expiration date of 07 May 2015. The BVARI IRB approved the study in continuing review in September 2013; HRPO approved this renewal in October 2013. In September 2013, the RAND IRB approved the study in continuing review; HRPO approved this renewal in October 2013. The RTI IRB approved the study in continuing review in March 2014; HRPO also approved this renewal. The University of Washington IRB approved the study in continuing review in August 2014 and is pending HRPO review.

Study investigators continued to participate in multiple routine weekly conference calls and other communications as necessary to ensure timely completion of all tasks throughout the year. RAND and RTI submitted updated SOW's to USAMRAA in February 2014; HJF submitted an updated SOW in March 2014. HJF, RAND, and RTI have responded to requests from our USAMRAA Contract Specialist (Mr. Lance Nowell) to revise the SOWs since submission. The STEPS UP team held a meeting with the DSMB in January 2014 to discuss study status. In February 2014, the DSMB finalized a report which summarized the first two DSMB meetings. We plan to hold the next DSMB meeting in the next quarter, once follow-up data collection is complete.

The study team continues to plan and prepare publications and presentations. The study team submitted a manuscript describing the overall design and methods of the STEPS UP study to *Contemporary Clinical Trials* in July 2014; investigators are preparing revisions to this manuscript. In preparation for the end of data collection this quarter, the team has begun drafting a manuscript describing the primary outcomes of the study; investigators expect to submit this manuscript to a high-impact journal once data collection and analysis are complete. A presentation titled "DoD STEPS-UP: Design, Roll-Out and Early Lessons from a Randomized Effectiveness Trial of Collaborative PTSD Care in Army Primary Care," was presented by Dr. Engel as a part of the symposium "Interventions for PTSD in Primary Care Medical Settings:

Implementation and Early Effectiveness Outcomes” at the 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), which was held in November 2013 in Philadelphia, PA. Dr. Freed, on behalf of study investigators, presented the STEPS UP study design at the Military Health System Research Symposium (MHSRS) in August 2014 in Ft. Lauderdale, FL. Additionally, a symposium titled “Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials” was accepted for presentation at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) which will be held in November 2014 in Miami, FL. As part of this symposium, Dr. Freed, Dr. Engel, and Dr. Jaycox will present on study-related topics including study design and early findings, results from the qualitative portion of the study, and suicide risk and correlates based on study eligibility data. Dr. Justin Curry, DHCC, will also present an overview of the implementation of the RESPECT-Mil program as part of this symposium.

During the past year, RTI continued ongoing routine maintenance and evaluation of the study website, conducted follow up assessments with study participants, and continued to refine strategies for obtaining follow-up assessments at each study location. RTI also engaged in data editing and preparation of data files and codebooks for the baseline, 3-month, 6-month and 12-month follow-up assessments.

In the past year, RAND completed data collection in the qualitative interview study portion of the trial. RAND completed all interviews with patients, care facilitators, and providers within the study. Once recruited, each patient was interviewed 3 times during the course of their participation in the study. In total, RAND recruited a total of 39 patients for the qualitative study and completed a total of 97 interviews with them (27 of the 39 patients completed all three interviews). In addition, RAND completed early phase qualitative interviews with eight nurse care facilitators and 7 late phase chart-assisted recall nurse care facilitator interviews (one care facilitator left the study early). RAND also completed 31 semi structured interviews with health care providers across the six study sites. RAND investigators continue to be involved in planning meetings, site visits, and conference calls. RAND has also been actively engaged in obtaining administrative data, working with HJF and RTI to develop procedures for data storage and transfer, examining codebooks to determine specific data requests. Partial data is being sought in the near term in order to prepare for data cleaning and analysis: M2 data has

been delivered while MDR and FIRST STEPS data are pending. Final administrative data will not be available until February 2015, allowing a 90-day window after study close for all medical care to be entered into the medical record system.

BVARI investigators continued to participate in weekly conference calls to discuss study procedures, recruitment, ongoing cases, and treatment issues. BVARI collaborators also continued telephonic consultation with the STEPS UP care managers as needed to provide additional clinical assistance for difficult cases and one-on-one training in clinical strategies. During the past year, BVARI collaborators continued participation in the weekly individual staffing calls with each STEPS UP care manager in order to help track study patients being staffed and record staffing notes. In addition, BVARI collaborators provided consultation to the study team on strategies to increase usage of the DESTRESS-PC web-based self-management site, provided usage estimates of the site for internal reporting, and worked with the Boston-based contractor to restore an administrative feature of the site to full functionality. BVARI collaborators will present on combat trauma types' relations with mental health using baseline data as part of a symposium at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2014, and are developing a manuscript based on this presentation.

During the past year, University of Washington collaborators continued more intensive supervision related to care management practices across all study sites. University of Washington investigators attended weekly telephone conferences to contribute to care manager coaching, intervention development, and general study implementation; they also continue to attend the University of Washington STEPS UP internal team meeting that is held approximately once each quarter. University of Washington collaborators continue to be involved in planning and preparing manuscripts and presentations.

As is the case in all clinical trials and longitudinal studies, retention is a full time concern. The predominantly young, male and highly mobile military demographic profile is a key issue. Our experience accomplishing controlled trials in this population has been an asset, and we have aggressively sought innovative retention strategies. During this past year, we held regular calls with all of the study Site PI's to discuss potential barriers to retention of participants in the study

and brainstorm solutions to address these barriers. These regular calls also helped investigators better understand local issues occurring at the sites that may have an impact on study participation.

During the next quarter, we plan to complete follow-up at the remaining study site (Ft. Campbell) and conduct data analyses on the full dataset. We will also continue to ensure compliance with all IRB administrative requirements and meet with IRB chiefs and HRPO representatives to coordinate an efficient process for ongoing regulatory submission and approval. We will continue care manager training and coaching at Ft. Campbell (the remaining site with participants) with individual staffing and group coaching calls as necessary, until data collection is complete. The study team will also continue work on multiple publications and presentations, and will prepare and disseminate materials to provide site, military, and MHS leaders with information about the trial results and the STEPS UP intervention program. Finally, we will begin working with the partial dataset of administrative health care data while awaiting final dataset next year.

#### **KEY RESEARCH ACCOMPLISHMENTS:**

There are not yet any clear scientific findings resulting from this research as we are still in the data collection phase. We anticipate completing data collection and conducting analyses in the next quarter.

#### **CONCLUSION:**

There are no conclusions to report at this time, as the study is still in the data collection phase. Investigators expect to complete data collection and conduct analyses in the next quarter.

## **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**

The following manuscript was submitted to *Contemporary Clinical Trials* in July 2014 and is pending revisions:

Engel CC, Bray RM, Jaycox L, Freed MC, Zatzick D, Lane ME, Brambilla D, Rae Olmsted K, Vandermaas-Peeler R, Litz B, Tanielian T, Belsher BE, Evatt DP, Novak LA, Unützer J, Katon WJ. Collaborative primary care for depression and posttraumatic stress disorder in the U.S. military health system: Design and baseline findings of a multisite randomized effectiveness trial.

The following was presented at the 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2013 in Philadelphia, PA:

Engel CC, Freed MC, Lane B, Jaycox L, Bray R, Zatzick D, Litz B. (November 2013). DoD STEPS-UP: Design, Roll-Out and Early Lessons from a Randomized Effectiveness Trial of Collaborative PTSD Care in Army Primary Care. Part of ISTSS Symposium: Interventions for PTSD in Primary Care Medical Settings: Implementation and Early Effectiveness Outcomes. Meredith L (chair) & Zatzick D (discussant). 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Philadelphia, PA.

The following was presented at the Military Health System Research Symposium (MHSRS) in August 2014 in Ft. Lauderdale, FL:

Freed M, Engel C, Bray R, Jaycox L, Zatzick D, Lane M, Brambilla D, Rae Olmsted K, Vandermaas-Peeler R, Litz B, Tanielian T, Belsher B, Evatt D, Novak L, Unutzer J, Katon W. (August 2014). Collaborative Primary Care for Depression and PTSD in the U.S. Military Health System: Design and Early Findings from STEPS UP, a Multisite Randomized Effectiveness Trial. Presented at Military Health System Research Symposium (MHSRS), Ft. Lauderdale, FL.

The following was accepted for presentation at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2014 in Miami, FL:

Wortmann, J. (November 2014). Mental Health Correlates of Combat and Operational Trauma Types among Active Duty Soldiers in Primary Care. Part of ISTSS Symposium: Prevalence and Correlates of Trauma Types among Service Members and Veterans with PTSD. 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

The following presentations were accepted as part of a symposium titled “Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials” at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2014 in Miami, FL:

Engel CC, Bray RM, Jaycox LH, Freed MC, Novak L, Tanielian T, Zatzick D, Katon W. (November 2014). Collaborative Primary Care for Depression and PTSD in the U.S. Military Health System: Design and Early Findings from a Multisite Randomized Effectiveness Trial. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

Jaycox L; Tanielian T, Farmer C, Woldetsadik M, Moen S. (November 2014). Qualitative Study of Soldiers within Primary-Care Interventions to Improve PTSD and Depression. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

Freed MC, Engel CC, Belsher B, Evatt D, Wortmann J, Novak L, Jaycox LH, Bray RM. (November 2014). Suicide Risk and Correlates to PTSD, Depression, and Alcohol Misuse in Military Primary Care Populations. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

Curry, J. (November 2014). RESPECT-Mil: Implementation of a Systems-Level Approach to Mental Health in Military Primary Care Settings. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

**INVENTIONS, PATENTS AND LICENSES:**

Nothing to report.

**REPORTABLE OUTCOMES:**

Nothing to report.

**OTHER ACHIEVEMENTS:**

Nothing to report.

**REFERENCES:**

Curry, J. C., Engel, C. C., & Zatzick, D. (in press). Stigma and barriers to care - collaborative care. In S. Cozza, M. Goldenberg, & R. Ursano (Eds.), *Clinical manual for the care of military service members, veterans, and their families*. Arlington, VA: American Psychiatric Publishing.

Zatzick, D., Rivara, F., Jurkovich, G., Russo, J., Geiss, S., Wang, J., et al. (2011). Enhancing the population impact of collaborative care interventions: mixed method development and implementation of stepped care targeting posttraumatic stress disorder and related comorbidities after acute trauma. *General Hospital Psychiatry*, 33, 123-134.

Engel C. C, T. Oxman, et al. (2008). Feasibility of collaborative care for depression and post-traumatic stress disorder in military primary care: The RESPECT-Mil Project. *Military Medicine*, 173(10), 935-940.

Tanielian, T. & Jaycox, L., Eds. (2008). "Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery." RAND/MG-720-

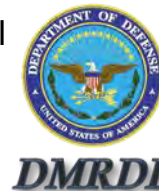
CCF (available at <http://veterans.rand.org>)

Litz, B. T., Engel, C. C., Bryant, R., & Papa, A. (2007). A Randomized, Controlled Proof-of-Concept Trial of an Internet-Based, Therapist-Assisted Self-Management Treatment for Posttraumatic Stress Disorder. *American Journal of Psychiatry*, 164(11), 1676-1683.

## **APPENDICES:**

N/A

# Stepped Enhancement of PTSD Services Using Primary Care (STEPS UP): A Randomized Effectiveness Trial DR080409/P1/P2, DoD Deployment Related Medical Research Program



**PI:** Michael C. Freed, PhD (Initiating PI)<sup>1</sup>; Robert M. Bray, PhD (Partnering PI)<sup>2</sup>; Lisa Jaycox, PhD (Partnering PI)<sup>3</sup>  
**Org:** <sup>1</sup>Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF); <sup>2</sup>RTI International; <sup>3</sup>RAND Corporation  
**Award Amount:**

## Study/Product Aim(s)

- **Primary Aim:** To evaluate whether, relative to Optimized Usual Care (OUC), STEPS UP will lead to greater improvements in PTSD and/or depression symptom severity.
- **Secondary Aims:** To evaluate whether, relative to OUC, STEPS UP will lead to greater improvements in somatic symptom severity, alcohol problems, mental health functioning, work functioning, costs, and satisfaction with care.

## Approach

This is a six-site, randomized controlled trial with follow-up assessments at 3, 6, and 12 months. Over a 2.5-year period, we enrolled 666 service members who screened positive for symptoms of PTSD and/or depression. This study will compare the STEPS UP intervention to OUC. OUC is RESPECT-Mil, a multi-site, primary care-based program where service members with symptoms of PTSD and depression are carefully screened, tracked, and treated within the primary care system, with the assistance and collaboration of a psychiatrist and an on-site nurse-level care manager. STEPS UP is testing possible enhancements to RESPECT-Mil, including:

- 1) Adding the option for centralized, telephone-based care management;
- 2) Adding care manager training in strategies to improve engagement in treatment and tools for early intervention;
- 3) Adding preference-based stepped care to existing options of pharmacotherapy that includes:
  - Web-based therapy options for PTSD and depression;
  - Telephone delivered therapy;
  - Possibly faster connection to face-to-face therapy by a specialist

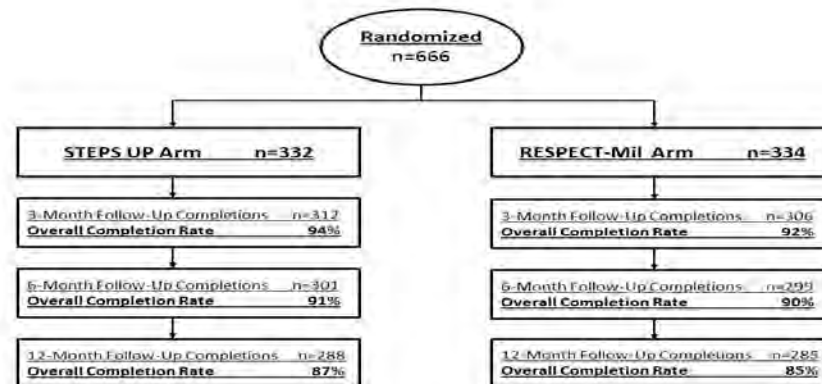


Figure: STEPS UP follow-up numbers through 31 AUG 2014

Accomplishment: Currently boasting high 12-month follow-up rates of 87% in the STEPS UP arm and 85% in the OUC arm. Only two participants remain in the 12-month follow-up data collection window. As soon as these two participants exit the window (no later than mid-October 2014), data collection will be complete.

## Timeline and Cost

Activities	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6 EWOFF
Intervention & protocol development/refinement						
Provider & expert panel interviews						
IRB submission/approval						
Hire staff & conduct training						
Recruit & consent participants						
Conduct data collection						
Analysis & writing						
Ongoing research team meetings						
Ongoing QA/QC procedures						
Submit reports						
<b>Estimated Budget (\$K)*</b>	<b>\$842K*</b>	<b>\$1,289K*</b>	<b>\$1,898K*</b>	<b>\$2,829K*</b>	<b>\$ 2,737K*</b>	<b>\$5,186K</b>
*Amount Spent						

## Goals/Milestones

### Year 1 Goals (Sept 2009-Aug 2010)

- ✓ Develop protocol, tools, manuals
- ✓ Provider interviews and collaborate with expert panel
- ✓ Submit to IRBs/obtain IRB approval
- ✓ Hold research team meetings
- ✓ Implement QA/QC procedures
- ✓ Submit reports

### Year 2 Goals (Sept 2010-Aug 2011)

- ✓ Refine protocol, tools, manuals
- ✓ Hire staff and conduct training
- ✓ Submit to IRBs/obtain IRB approval
- ✓ Ongoing research team meetings
- ✓ Ongoing QA/QC procedures
- ✓ Continue to submit reports

### Year 3 Goals (Sept 2011-Aug 2012)

- ✓ Amend protocol, tools, manuals
- ✓ Continue to hire staff and conduct training
- ✓ Submit to IRBs/obtain IRB approval
- ✓ Recruit and consent participants (began Feb 12)
- ✓ Conduct data collection (began Feb 12)
- ✓ Ongoing research team meetings
- ✓ Ongoing QA/QC procedures
- ✓ Continue to submit reports

### Year 4 Goals (Sept 2012-Aug 2013)

- ✓ Continue to recruit and consent participants
- ✓ Continue data collection
- ✓ Analysis and writing
- ✓ Ongoing research team meetings
- ✓ Ongoing QA/QC procedures
- ✓ Continue to submit reports

### Year 5 Goals (Sept 2013-Aug 2014)

- ✓ Continue data collection for follow-up assessments
- ✓ Continue analysis and writing
- ✓ Ongoing research team meetings
- ✓ Ongoing QA/QC procedures
- ✓ Continue to submit reports

### Year 6 EWOFF Goals (Sept 2014-Aug 2015)

- Complete follow-up data collection
- Continue analysis and writing
- Ongoing research team meetings
- Ongoing QA/QC procedures
- Continue to submit reports

## Comments/Challenges/Issues/Concerns

- IRB approval delays have been impediments in starting up sites and beginning recruitment/enrollment
- Focus on intensifying follow-up efforts to obtain excellent follow-up rates
- Due to multiple start-up delays, investigators will need a 1-year extension without funds (EWOFF) to meet current deliverables.

## Budget

Expenditures to Date (Year 1 – Year 5): TOTAL: \$9,595K (HJF: \$4,197K; RTI: \$4,242K; RAND: \$1,156K)

Projected Expenditures Year 6 EWOFF: TOTAL: \$5,186K (HJF: \$2,565K; RTI: \$686K; RAND: \$1,935K)